



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

March 16, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-37

Fredrick C. Michael, Owner
Chet's Custom Foods, Inc.
4124 Main Street
Springfield, Oregon 97478

WARNING LETTER

Dear Mr. Michael:

We inspected your firm located at 4124 Main Street, Springfield, Oregon, on February 20, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your tuna sandwich products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations of concern were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for tuna sandwich products to control the food safety hazards of allergens and pathogen survival during refrigerated storage. This same violation was brought to your attention during our last inspection on March 14, 2000, and in a letter to you from the FDA dated March 30, 2000.
2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for all eight areas of sanitation. This violation has also been ongoing since your last inspection and documented in the March 30, 2000 letter to you. You could not provide our investigator with monitoring records for the following eight areas of sanitation:

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- a. Safety of water;
- b. Condition and cleanliness of food contact surfaces;
- c. Prevention of cross-contamination;
- d. Maintenance of hand washing, hand sanitizing, and toilet facilities;
- e. Protection from adulterants;
- f. Proper labeling, storage, and use of toxic compounds;
- g. Control of employees with adverse health conditions; and
- h. Control of pests.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written in a cursive style.

Charles M. Breen
District Director